



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2013-N-0093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0746. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications (NME NDAs) and Original Biologics License Applications (BLAs) in Prescription Drug User Fee Acts (OMB Control Number 0910-0746)--  
Extension

As part of its commitments in the Prescription Drug User Fee Act (PDUFA) V, FDA established a new review Program to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applies to all NME NDAs and original BLAs that are received from October 1, 2012, through September 30, 2017. The Program is described in detail in section II.B of the document entitled “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017” (the Commitment Letter) (available at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>).

The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the Program is an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The PDUFA V Commitment Letter specifies that the assessments be conducted by an independent contractor and that they include interviews of pharmaceutical manufacturers who submit NME NDAs and original BLAs to the Program in PDUFA V. The

contractor for the assessments of the Program is Eastern Research Group, Inc. (ERG), and the statement of work for the assessments is available at

<http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM304793.pdf>.

In accordance with the PDUFA V Commitment Letter, FDA contracted with ERG to conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing review transparency and communication during the review process. ERG will anonymize and aggregate sponsor responses prior to inclusion in the assessments and any presentation materials at public meetings. FDA will publish ERG's assessments, with interview results and findings, in the Federal Register for public comment.

Description of Respondents: The respondents to this collection of information are sponsor representatives for NME NDAs and original BLAs.

In the Federal Register of December 10, 2015 (80 FR 76699), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Portion of Study	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pre-test	5	1	5	1.5	7.50
Interviews	135	1	135	1.5	202.50
Total					210

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA typically reviews approximately 40 to 45 NME NDAs and original BLAs per year. ERG interviews 1 to 3 sponsor representatives at a time for each application that receives a first-cycle action from FDA, up to 135 sponsor representatives per year. ERG conducts a pretest of the

interview protocol with five respondents. FDA estimates that it will take 1.0 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. We estimate that up to 135 respondents will take part in the post-action interviews each year, with each interview lasting 1.0 to 1.5 hours, for a total of a maximum of 202.5 hours. Thus, the total estimated annual burden is 210 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: July 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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